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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/513,086	02/24/2000	Linda S. Mansfield	MSU 4.1-458	4724

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EXAMINER
WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
1632	

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17

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary	Application No. 09/513,086	Applicant(s) Mansfield et al.
	Examiner Joseph T. Woitach	Art Unit 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Aug 13, 2002*

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-9, 13-17, 45, 46, 49, and 50* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideratio

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-9, 13-17, 45, 46, 49, and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examine

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some* c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This application filed February 24, 2000, claims benefit to provisional application 60/152,193, filed September 2, 1999.

Applicants' Appeal brief filed August 13, 2002, paper number 16 has been received and entered. Claims 4-9, 13-17, 45, 46, 49 and 50 are pending and currently under examination.

Upon re-evaluation of the pending claims new grounds of rejection not previously addressed during the prosecution will be made of record. **PROSECUTION IS HEREBY REOPENED**. The finality of the previous Office action is hereby withdrawn. New grounds of rejection are set forth below.

Claim Objections

Claims 4, 13 and 45 are objected to because of the following informalities: each of the indicated claims recite and encompass use of the instantly claim vaccine in "an equid". An equid is noun however the term refers to the family *Equidae*, not an individual subject. Amending the claims to encompass "an equine" would obviate the basis of the objection.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-9, 13-17, 45, 46, 49 and 50 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Previously, Applicants state that the claims are drawn to an antigen vaccine and argue that the present invention can provide protection by producing antibodies *in vivo* which interfere with the function of surface proteins of *Sarcocystis neurona* which enable the organism to enter the nervous system or CSF. Applicants argue that Liang *et al.* cited in the previous office action recognizes that Sn16 may be an important in a vaccine but does not suggest the use of recombinant proteins. Further, it is argued while Liang *et al.* suggest that Sn30 does not serve as an antigen, that the instant specification supports a possible role for Sn30 because of its ability to interfere with the Sn30 surface proteins function. In addition, Applicants argue that the vaccine trials by Fort Dodge supports the premise that a vaccine to *Sarcocystis neurona* can be developed despite the production of antibodies to whole cells and Liang *et al.* represent an invitation to experiment and does not suggest that a recombinant vaccine is produced.

In the Appeal Brief, Applicants admit that neither the amino acid sequence nor polynucleotide sequence is disclosed, however it is argued that methodology and materials to isolate said sequences are clearly described. Applicants attempt to distinguish the instant case from that in *Eli Lilli* and *Enzo*, in that the breadth of the instant claims is drawn to only *Sarcocystis neurona*, not any potential organism. See Appeal Brief pages 10-11. Applicants arguments have been fully considered but not found persuasive.

As noted previously, Stedman's Medical Dictionary defines a vaccine as essentially any preparation intended for active immunological prophylaxis. First, Applicant states that the present vaccine does not prevent the *Sarcocystis neurona* from infecting the equid (page 3; first full paragraph, first line), however the claims clearly recites the limitation of a 'vaccine for active immunization of an equid against a *Sarcocystis neurona* infection' (claim 4). Examiner agrees with Applicants arguments that antibodies to Sn30 antigen may serve as vaccine in contrast to what Liang *et al.* teach based on the *in vitro* analysis presented in the instant specification, however the ability of antisera *in vitro* to interfere with surface proteins function does not seem to be extendable to *in vivo*. First all the samples analyzed by Liang *et al.* are samples form horses with a clinical diagnosis of neurologic disorder resembling EPM (page 1834; bottom of second column). Liang *et al.* clearly show that most of the samples maintain an immune response to Sn30 and Sn16, and that antisera from these animals are able to neutralize *S. neurona* infectivity *in vitro* (page 1836; results summarized in figure 4). However, all the animals were clinically diagnosed with some form of neurological disorder, and so one would of ordinary skill

in the art would conclude that even the presence of antibodies to Sn30 and Sn16 in an animal would not prevent the spread of *S. neurona* to the nervous system or the CSF. The specification provides evidence that antibodies to Sn30 and Sn16 can stop infection *in vitro,* however there is no evidence that they would serve as a vaccine *in vivo.* Applicants admit that the present invention does not prevent infection of equid and have not provide evidence that the invention prevents the spread of *S. neurona* to the nervous system and CSF.

With respect to arguments differentiating the present application from the fact pattern of *Eli Lilli* and Enzo, Examiner agrees that the opinion of the court provides a clear indication that a single species does not provide adequate written description for the genus, however not even one species is defined in the present specification. It is noted that the courts have found that adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). In the instant case, Examiner would agree that methodology to isolate any protein may be routine and would note that courts have held possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.,* 48 USPQ2d 1641, 1646 (1998). The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" *Vas-*

Cath Inc. v. Mahurkar, 19USPQ2d at 1117. As admitted by Applicants, the present disclosure is silent with respect to either the amino acid or polynucleotide sequences encompassed and required by the invention to make and use a recombinant antigen. The fact that the instant invention is drawn to only the antigens from one parasite *S. neurona* versus a genus is irrelevant because there is no support for even this species. The artisan can not envision any of the particulars of the sequences encompassed by the instant claims, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method used. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *(Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116).

Thus, for the reasons above and of record, the rejection is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-9, 13-17, 45, 46, 49 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claims 4, 13 and 45 are unclear in the recitation of "an equid" because this term refers to the family *Equidae*, not an individual equine. It is unclear if the vaccine and methods of use

must affect the entire family or if it is directed to affecting individual equine. Amending the claims to encompass "an equine" would obviate the basis of the objection.

Claim 7 recites the limitation "the antigen" in lines 3 and 4, however claim 4 from which it depends recites two different antigens. There is insufficient antecedent basis for this limitation in the claim. It is unclear to what antigen in claim 4 "the antigen" refers. It is not clear if it encompasses the use of both or the use of each of the separate and single antigens. Further, there is only "a fusion polypeptide" and it is unclear if each antigen is comprise in one protein or if separate fusion proteins containing each antigen is encompassed by the claim.

Claims 14 and 15 recites the limitation "the recombinant antigen" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claims 14 and 15 depend on claim 13, however neither claim explicitly sets forth that the antigen is a recombinant antigen. The claim is unclear and confusing because claim 13 recites that the composition consists essentially of the specific antigens, however claim 14 indicates that it is recombinant and given the general teaching of the specification includes forms of a fusion protein similar to that set forth in claims 7 and 8.

Claim 17 recites the limitation "the DNA" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 17 depends on claims 15 and 13, however none of the claims explicitly set forth a DNA or provide support for the claims as they are drawn to a plasmid in a microorganism.

Claim 46 recites the limitation "and/or" in line 2. There is insufficient antecedent basis for this limitation in the claim. The claim is confusing because claim 45 recites that an immune response to both the 16 kDa and 30 kDa antigens is produced, not one or the other separately. It is unclear how one antigen could be delivered and provide an immune reaction to both potential antigens.

Claim 49 recites the limitation "and/or" in line 2. There is insufficient antecedent basis for this limitation in the claim. The claim is confusing because claim 45 recites that an immune response to both the 16 kDa and 30 kDa antigens is produced, not one or the other separately. It is unclear how one antigen could be delivered and provide an immune reaction to both potential antigens.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Liang *et al.* (Infect. Immun., 1998).

Previously, the rejection was withdrawn because the claims were amended to encompass a recombinant antigen, not an endogenous antigen. Presently, the claims broadly encompass any composition comprising the 30 kDa and 16 kDa antigen of *Sarcocystis neurona* and any administration of said composition. In the instant case the parasite *S. neurona* itself would anticipate the composition of claim 4, and administration of said parasite would anticipate the method of claim 13. This interpretation of the breadth of the claim is consistent with Applicants' arguments that the embodiments of the claims include "the entire *Sarcocystis neurona* organism" (see Appeal Brief, page 11, first full paragraph).

Liang *et al.* teach that *S. neurona* contains the 30 kDa and 16 kDa antigens encompassed by the claims (see for example figure 3). Further, Liang *et al.* teach that horses exposed to *S. neurona* have a relatively low incidence of clinical EPM, and that the exposure to *S. neurona* may induce a protective immunity and prevent the entry into the central nervous system halting the presentation or progression of the disease (page 1834; top of second column).

Conclusion

No claim is allowed.

Claims 5-9, 14-17, 45-46, 49 and 50 are free of the prior art of record, however the claims are subject to other rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Pauline Farrier whose telephone number is (703)305-3550.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach

Deborah Crouch

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